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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/390,268	09/03/1999	TOM WESTBERG	F-5481	6635

7590 08/01/2003

Bradford R L Price  
Baxter Healthcare Corporation  
Fenwal Division RLP-30  
Route 120 & Wilson Road  
Round Lake, IL 60073

EXAMINER

DEAK, LESLIE R

ART UNIT	PAPER NUMBER
3762	14

DATE MAILED: 08/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

EC

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/390,268	WESTBERG ET AL.
	Examiner Leslie R. Deak	Art Unit 3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 29 May 2003.

2a) This action is FINAL.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 11-38 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 11-38 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 03 September 1999 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>13</u> .	6) <input type="checkbox"/> Other: _____

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 11-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,628,908 to Kamen et al in view of US 5,462,416 to Dennehey et al. Kamen discloses a disposable cassette for use in a dialysis system. Kamen's cassette 24 includes preformed wells and channels that serve as separate pump chambers P1 and P2, liquid paths F1 and F2, and a cycler 14 that applied positive and negative pressure to open and close the valves in the cassette (column 7, lines 52-63, column 8, lines 53-67). Further, Kamen discloses a controller that interacts with the cycler and the fluid delivery system to perform a selected fluid delivery procedure (column 5, lines 47-51). Kamen fails to disclose a set of specific fluid paths or a third pump. Dennehey discloses a fluid cassette for blood processing systems with a cassette 22 with multiple liquid paths F<sub>N</sub> and valve stations V<sub>N</sub> (column 6, lines 61-66). Dennehey discloses that the number and arrangement of the paths and valves may vary within the system (column 7, lines 4-8), and the cassette links with pumps in the processing system to carry out the desired procedure (column 6, lines 6-13). Further, Kamen discloses that the controller can operate first and second actuating networks 230 and 232 in tandem or independently to pump liquids between variable sources and destinations (column 19,

lines 38-47). Kamen discloses that a preferred embodiment of his invention includes pneumatically actuated pumping action, indicating that Kamen contemplated other pumping means in the development of his invention (see column 3, lines 43-45). Further, Dennehey discloses that his invention serves to provide a self-contained pumping and valving element that is completely sealed for operation (see column 2, lines 44-48). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to add an additional pumping station and variable fluid pathways as disclosed by Dennehey to the variably programmed fluid cassette disclosed by Kamen in order to create a self-contained pumping and valving element that is completely sealed for operation with multiple variable fluid paths, as taught by Dennehey.

3. Claims 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,628,908 to Kamen et al in view of US 5,462,416 to Dennehey et al in view of US 5,795,317 to Brierton et al. The modified programmable, variable Kamen device is able to perform the blood processing process as claimed, but does not set forth the specific steps of the process. Brierton discloses and claims extracorporeal blood processing methods and apparatus that is capable of running several fluid flow procedures in order to separate the blood. In particular, Brierton discloses that his apparatus allows blood to pass through a needle assembly 30 to a cassette 110 (which includes all the fluidly connected pumping and valving stations) and on to a processing module 352, where the blood is separated. The platelet stream exits the separation module back through the cassette and at least a portion of it is collected in assembly 80, diverted to reservoir 150, or returned to the patient 4. Further, separated plasma exits the separation device

through the cassette for storage in tubing 90 or reservoir 150, and red blood cells also flow from the separation device through the cassette to a reservoir. Brierton discloses that the cassette and separation chamber contemplated by his invention defines a closed and sterile system that reduces the impact of separation on the patient cells. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to adapt the modified programmable, variable Kamen device to include the multiple separation modes and processes disclosed by Brierton in order to provide a closed and sterile system for blood processing that allows variation in the flow paths and their connection, as taught by Brierton and Dennehey.

#### ***Response to Arguments***

4. Applicant's arguments with respect to claims 11-34 have been considered but are moot in view of the new ground(s) of rejection.
5. With regard to applicant's argument regarding the motivation to combine the Kamen reference with Dennehey and Brierton, Kamen discloses that pneumatic pumping stations are merely a preferred embodiment of his invention, indicating that other pumping means are contemplated as within the scope of the invention. As such, the pumping means of the Dennehey and Brierton references are contemplated as within the scope of the Kamen reference, and are easily substituted with the pneumatic pump stations disclosed by Kamen in order to provide a closed and sterile processing environment.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 703-305-0200. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703-308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0873.

  
Ird  
July 31, 2003

ANGELA D. SYKES  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700